SEP 18 2007

K072322

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

ULTRA FAST-FIX Meniscal Repair System & ULTRA FAST-FIX AB Meniscal Repair System

Date Prepared: 31 AUG 2007

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Julie Acker, RAC

Regulatory Affairs Specialist

Phone: (508) 261-3618

FAX: (508) 261-3620

C. Device Name

Trade Name:	ULTRA FAST-FIX Meniscal Repair System ULTRA FAST-FIX AB Meniscal Repair System
Common Name:	Meniscal Repair Device
Classification Name:	Suture Retention Device/Synthetic Nonabsorbable Polyethylene Suture
Product Code:	GAT
Regulation Number:	21 CFR §878.5000
Device Class	II
Panel	Orthopedic

D. Predicate Devices

The Smith & Nephew ULTRA FAST-FIX and ULTRA FAST-FIX AB Meniscal Repair systems are substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution: Smith & Nephew FAST-FIX (K002261) and FAST-FIX AB (K020480) Meniscal Repairs Systems.

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E. Description of Device

The Smith & Nephew ULTRA FAST-FIX and ULTRA FAST-FIX AB Meniscal Repair Systems are all-inside meniscal repair devices. Each device includes two implants, pre-tied with #0 nonabsorbable suture pre-loaded into a needle delivery system. The FAST-FIX Meniscal Repair System is provided sterile for single use only.

F. Intended Use

The Smith & Nephew ULTRA FAST-FIX Meniscal Repair Systems and ULTRA FAST-FIX AB Meniscal Repair Systems are intended for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

G. Comparison of Technological Characteristics

The Smith & Nephew ULTRA FAST-FIX and ULTRA FAST-FIX AB Meniscal Repair Systems are substantially equivalent in design, intended use and fundamental scientific technology to the predicate Smith & Nephew FAST-FIX (K002261) and FAST-FIX AB (K020480) Meniscal Repairs Systems. The component material changes defined in this premarket application have been demonstrated to be substantially equivalent and raise no new issues of safety and efficacy.

H. Summary Performance Data

Performance testing demonstrates that the soft tissue repair achieved using ULTRA FAST-FIX and ULTRA FAST-FIX AB is substantially equivalent to repair achieved with currently marketed meniscal repair devices. Performance testing also affirms that ULTRA FAST-FIX and ULTRA FAST-FIX AB offer substantially equivalent suture sliding characteristics compared to the predicate FAST-FIX and FAST-FIX AB devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 2007

Smith & Newphew, Inc.
% Ms. Julie Acker, RAC
Regulatory Affairs Specialist
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K072322
Trade/Device Name: ULTRA FAST-FIX Meniscal Repair System
ULTRA FAST0-FIX AB Meniscal Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: August 16, 2007
Received: August 20, 2007

Dear Ms. Acker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072322

Device Name: ULTRA FAST-FIX Meniscal Repair System

ULTRA FAST-FIX AB Meniscal Repair System

The Smith & Nephew ULTRA FAST-FIX Meniscal Repair Systems and ULTRA FAST-FIX AB Meniscal Repair Systems are intended for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

Prescription Use ___X_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072322